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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,578	04/27/2006	Takuji Kawai	10921.402USWO	6678

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EXAMINER	
SODERQUIST, ARLEN	
ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
06/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,578	KAWAI, TAKUJI	
	Examiner	Art Unit	
	Arlen Soderquist	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-27-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nankai (JP 8-10208) as described on page 1, line 10 to page 2, line 21 and shown in figures 11A, 11B and 12 of the instant specification in view of Burke (US 7,338,639). Page 1, line 10 to page 2, line 21 of the instant specification teach that a disposable glucose sensor is often utilized in an easy method to measure the glucose level in blood, (see JP 08-10208 B, Nankai for example). For instance, the glucose sensor may be designed to output the response current, which is necessary for computing the blood glucose level, when it is mounted to an analytical apparatus. In the analytical apparatus, the magnitude of the response current is determined by utilizing a double integration circuit including a capacitor, and the blood glucose level is computed based on the determined response current. As shown in figures 11A and 11B, the magnitude of the response current is determined based on the discharge time (T_2) of the capacitor after the capacitor is charged with the electric charge related with the response current for a predetermined time period (T_1). As shown in figure 12, the determination of the response current is performed at predetermined time intervals (t). On the other hand, the response current (I_1) for computing the blood glucose level is sampled at the time (t_1) after a predetermined time period has elapsed from the time (t_0) when the supply of the blood to the glucose sensor was confirmed. The blood supply to the glucose sensor is confirmed by checking whether or not the response current measured exceeds a predetermined threshold (I_2). To accurately determine the response value by

the method utilizing the double integration circuit, it is preferable to set the charge time (T_1) of the capacitor relatively long. Therefore, for the measurement accuracy of the response current, the time interval (t) for measuring the response current need be set relatively long. As will be understood from figure 12, in the initial stage in which the blood is supplied to the glucose sensor, the response current increases sharply. Therefore, in the case where the time interval (t) for measuring the response current is set long, the time when the blood is supplied cannot be determined accurately. Due to such inaccuracy, the time period from when the sample is supplied till when the response current for the computation is sampled may vary among the measurements, which may degrade the measurement accuracy of the blood glucose level. As taught above Nankai does not teach at least two different times between measurement of the response curve with the first shorter time occurring until sample detection has occurred and the second longer time occurring thereafter.

In the patent Burke teaches a method of measuring an analyte in a biological fluid by applying an excitation signal having a DC component and an AC component to the sensor as shown in figures 3A-3B having two electrodes and a reagent. The AC and DC responses are measured; a corrected DC response is determined using the AC response; and a concentration of the analyte is determined based upon the corrected DC response. Figure 1 shows the excitation sequence and typical response (102) for one preferred method applied to a sample of whole blood mixed with an appropriate reagent. Figure 1 and the method used are described in column 6, line 39 to column 8, line 9. In the preferred excitation signal embodiment of figure 1, DC excitation and four frequencies of AC excitation are used. A relatively high frequency signal (between about 10 kHz and about 20 kHz with an amplitude between about 12.4 mV and about 56.6 mV) is applied, at a start time (101). A frequency of 20 kHz is used in the example of figure 1, but other values may be due to various parameters such as cell geometry and the particular cell chemistry. At the time a test strip is inserted into the meter (110), several possible responses to the insertion of the test strip into the glucose meter are shown depending on the state/suitability (wet or dry) of the test strip. Once a suitable test strip has been inserted, the user doses the strip, as shown at time 120. While the blood sample is covering the electrodes the current response will rapidly increase, as the glucose reacts with the reagent and the contact area increases to maximum. The response current will reach a stable state, which indicates the

impedance of the sample at this frequency. Once this measurement is made and recorded by the test meter, the excitation frequency is then stepped down to about 10 kHz in the preferred embodiment, as shown at time 130. Another measurement is made and recorded by the test meter, and the frequency is stepped down to about 2 kHz in the preferred embodiment, as shown at 140. A third measurement is made and recorded by the test meter at this frequency. A fourth measurement is made at about 1 kHz in the preferred embodiment, as shown at 150. In the preferred embodiment, measurements are taken at regular intervals (e.g. 10 points per cycle). It will be appreciated that the stable state response may be measured as current or voltage (preferably both magnitude and phase) and the impedance and/or admittance can be calculated therefrom. Although the present specification and claims may refer alternately to the AC response as impedance or admittance (magnitude and/or phase), resistance, conductivity, current or charge, and to the DC response as current, charge, resistance or conductivity, those skilled in the art will recognize that these measures are interchangeable, it only being necessary to adjust the measurement and correction mathematics to account for which measure is being employed. In the preferred embodiment, the test meter applies a voltage to one electrode and measures the current response at the other electrode to obtain both the AC and DC response. In alternative embodiments measurements are made at fewer or more frequencies. Preferably measurements are made at at least two AC frequencies at least an order of magnitude apart. If more than two AC frequencies are used, then it is preferable that the highest and lowest frequencies be at least an order of magnitude apart.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the Nankai method and apparatus with the teachings of Burke and used a higher measurement (signal sampling) frequency prior to and shortly after sample dosing followed by a lower measurement frequency after that as taught by Burke because of the ability to better measure various parameters and/or components of the sample at different frequencies as taught by Burke.

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to biosensing devices using electrodes and a reagent to measure components of body fluids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571)272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Arlen Soderquist/
Primary Examiner, Art Unit 1797